DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127 1611

August 20, 2002

VIA FEDERAL EXPRESS—NEXT DAY

Robert F. Wilson, President
Seafood Systems, LLC
1504 Vultee Blvd.
Nashville, TN 37217

Warning Letter No. 02-NSV-34

Dear Mr. Wilson:

We inspected your firm located at 1504 Vultee Blvd., Nashville, TN, on June 26-29 and July 1, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, most of which were previously brought to your attention in our letters dated September 4, 2001 and December 3, 2001, cause your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood HACCP information is available through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. The following problems were noted with your HACCP plan to control scombrotoxin formation in histamine producing fish:

- Your HACCP plan must list adequate critical limits that must be met for the receiving and processing critical control points, to comply with **21 CFR 123.6(c)(3)**. Your HACCP plan for the receiving and processing critical limit states that the internal temperature of histamine producing fish may not exceed 45°F.

- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with **21 CFR 123.7(b)**. The corrective actions listed in your HACCP plan for the receiving critical control point and the processing critical control point are not adequate. Your corrective action at the receiving critical control point relies on visual inspection for decomposition to determine the acceptability of the fish. Visual inspection alone is not a reliable method for the detection of histamine.

- You must implement the monitoring procedures listed in your HACCP plan, to comply with **21 CFR 123.6(b)**. However, your firm does not routinely take product temperature upon receipt. Your firm's routine practice is to place product in the cooler upon receipt and measure the temperature, as

long as six hours later. Furthermore, your firm did not maintain monitoring records of product receiving temperatures from May 23, 2002 to June 21, 2002.

- Your HACCP plan must list adequate recordkeeping procedures for monitoring the receiving and processing critical control points, to comply with **21 CFR 123.6(c)(7).**

2. You must have a written HACCP plan to control each food safety hazard that is reasonably likely to occur, to comply with **21 CFR 123.6(b)**. However, your firm does not have a HACCP plan to address the hazard of parasites in fish intended to be consumed raw and the hazard of drugs in aquacultured seafood products. In addition, your firm does not have a HACCP plan to address the hazard of chemicals in shellstock.

3. You must have a written HACCP plan that lists verification steps that are adequate, to comply with **21 CFR 123.6(c)(6).** Your firm's HACCP plans do not require a review of monitoring, corrective action and verification records within one week of preparation.

4. The verification step listed in your HACCP plan to control chemicals in your aquacultured seafood products is not adequate, to comply with **21 CFR 123.6(c)(6).**

5. Your HACCP plan must be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official in your firm, to signify that the plan has been accepted for implementation by your firm, to comply with **21 CFR 123.6(d).**

6. Your firm has not calibrated your thermometers, to comply with **21 CFR 123.8(a)(2)**.

7. You must adequately monitor sanitation conditions and practices during processing, to comply with **21 CFR 123.11(b)&(c)**. Your firm does not routinely maintain sanitation records as stated by your employee. Furthermore, when sanitation records were requested only one record (dated May 7) was provided to the investigators.

This letter may not list all the deviations at your firm. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you have taken to correct the violations. For corrections that you cannot complete within fifteen (15) working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made and that you explain your plan for preventing these violations in the future.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
Director, New Orleans District

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